6/15/98

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

d1850b

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106
Telephone: 215-597-4390

WARNING LETTER

GEN. SPEC
RELEASE
F# _____ DATE 6/8/98
Reviewed by: RC Cherry, CO

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

98-PHI-23

June 8, 1998

Mr. Anthony J. Madison
General Manager
Medical Components, Inc.
MEDCOMP
1499 Delp Drive
Harleysville, PA 19438

Dear Mr. Madison:

On March 31, 1998, and April 1,2,6,9,20, 1998, Food and Drug Administration (FDA) Investigator Ronald Stokes and Compliance Officer Richard C. Cherry conducted an inspection at your Harleysville, PA, facility. Your firm manufactures catheters, specifically, the Tesio hemodialysis catheter. These products are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), and as such are subject to the requirements of Title 21 Code of Federal Regulations (21 CFR), including, but not limited to the Quality System Regulation, set forth at 21 CFR part 820.

At the conclusion of the inspection an FDA-483 List of Inspectional Observations was issued to and discussed with you listing deviations to the Quality System Regulation.

Your devices are adulterated within the meaning of section 501(h) of the Act [21 U.S.C. §351(h)], in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation, are not in conformance with the Quality System Regulation, as follows:

> Failure to ensure that the quality system requirements are effectively established and maintained [21 CFR § 820.20].

At least 20 devices (Tesio hemodialysis catheters/adapter portion) have malfunctioned after distribution. These device failures have resulted in 4 deaths and at least 16 serious

injuries. All of the device failures have involved the [redacted] portion of the adapter which has undergone a materials change to [redacted]. At least 7160 units have been distributed with the [redacted] change. The failures occurred, because the [redacted] bond between 2 components of the extension (male portion of the adapter and the [redacted] tube) did not hold as specified. These parts came apart while connected to the patients causing blood loss in all 20 cases.

> Failure to ensure that all complaints are processed in a uniform and timely manner [21 CFR § 820.198].

Your firm did not take appropriate timely steps to obtain additional information from complainants in an effort to determine the cause of the catheters' failure, specifically, where or what portion of the catheters failed. For example, between February 24 and March 17 of this year [redacted] complaints were received including 3 deaths. It was not until March 16 that you sent a fax to a user facility to ask them where the failure (separation point) occurred.

> Failure to establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met [21 CFR § 820.75].

Your firm does not routinely or periodically conduct post-sterilization stress tests, such as pull and leak tests, on the Tesio extension prior to distribution, even after a change in materials occurred in the [redacted] portion of the extension adapter.

At the conclusion of the inspection, you promised to send a written response to the FDA-483, to the District Office by April 24, 1998. We acknowledge receipt of your letter dated April 23, 1998, and your representations concerning corrective actions. Your corrective activities will be evaluated during the next inspection of your facility.

We disagree, however, with your position that the failures were unpredictable and could not have been anticipated. We believe that appropriate testing, similar to that accomplished during your investigation of the complaints, would have revealed the incompatibility between the [redacted] and the existing bonding [redacted]. Additionally, while we can appreciate your dilemma (insufficient information provided to you by the complainants presented an obstacle that impeded a more timely

evaluation of the problem) we feel that you should have, and could have, made an attempt to obtain additional information faster than you did. That is, the nature of the product and the physical condition of the patients who use the device, warranted a more thorough follow-up. Finally, you state that MEDCOMP does conduct post-sterilization testing. If you are implying that the FDA-483 observation #3 is not valid, then we disagree. Post-sterilization testing conducted only during the validation phase of the design control process, is not sufficient. You should, at minimum, conduct post-sterilization finished product testing on a periodic basis.

We understand that you have been in contact with the Philadelphia District Recall and Emergency Coordinator (R & E), with regard to the recall of the Tesio hemodialysis catheters, and the Center for Devices and Radiological Health (CDRH) regarding your proposed labeling changes and other issues. Please continue your discussions and correspondence with R & E and CDRH for these specific items.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should take prompt action to correct any manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a later comprehensive follow-up inspection, and may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing with fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to the

underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the attention of Richard C. Cherry, Compliance Officer, at the address noted above.

Sincerely,

John Thorsky
Acting District Director
Philadelphia District

cc: Pennsylvania State Department of Health
132 Kline Plaza, Suite A
Harrisburg, PA 17104
Attention: Robert E. Bastian, Director
Division of Primary Care and
Home Health Services